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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09 380,377	09 16 1999	NPH J BULLFID	39-189	2543

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EXAMINER
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WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 02 20 2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b>	Application No. <b>09/380,377</b>	Applicant(s) <b>Bulleid, N.J.</b>
	Examiner <b>Joseph T. Woitach</b>	Art Unit <b>1632</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Feb 11, 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. X A Notice of Appeal was filed on Sep 10, 2001. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.
3. X The proposed amendment(s) will not be entered because:
  - (a) X they raise new issues that would require further consideration and/or search. (See NOTE below);
  - (b) they raise the issue of new matter. (See NOTE below);
  - (c) they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: See attached.

4. Applicant's reply has overcome the following rejection(s):  
\_\_\_\_\_  
\_\_\_\_\_

5. Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claim(s).

6. X The a) affidavit, b) exhibit, or c) X request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See attached.  
\_\_\_\_\_

7. The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

8. X For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):

Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: \_\_\_\_\_

Claim(s) rejected: 1-11, 13-25, and 28-30 \_\_\_\_\_

9. The proposed drawing correction filed on \_\_\_\_\_ a) has b) has not been approved by the Examiner.

10. Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

11. Other:

*Deborah Crouch*  
**DEBORAH CROUCH**  
**PRIMARY EXAMINER**

*GROUP 1877/130*

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Response to After Final amendment:

Section 3(a):

The proposed amendments raise new issues under 35 USC 112, first and second paragraph and possibly 35 USC 102, which would require further consideration. Specifically, in the recitation of 'said pro- $\alpha$  chain for assembly into said first procollagen with other pro- $\alpha$  chains having said activity' is unclear since at least two types of pro- $\alpha$  chains are recited in (i) and (ii) above. Further, the recitation said activity lacks antecedent basis to pro- $\alpha$  chains since the only previous reference is to an activity of a 'first moiety' in (i).

Section 6(c):

With respect to the rejections of record, Applicants arguments have been fully considered but not found persuasive for the reasons of record.

With respect to the obvious double patenting, claims 13-19 of '827 clearly encompass a method of producing collagen in a host cell. In light of the definition of the various cells types which are encompassed by a host cell, the specification teaches that a host cell can express other procollagen molecules. Therefore, in light of the teaching in the specification, the instant claims reciting 'expresses a second procollagen' would be obvious.

With respect to enablement of method claims, Applicants point to fact that the instant claims recite similar language to that of '827. Further, it is argued that the cited references only provide examples of particular constructs failure to assemble. It is noted that the proposed claim

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language and pending claims are similar to that of '827, however the instant application and pending claims are considered for what is now claimed. In the basis of the rejection, at the time of the claimed invention the references provide evidence that simply swapping domains in collagen molecules will not immediately result in assembly of functional molecules. Though a method claim may encompass some non-working embodiments, the specification must provide the necessary guidance to the invention in the scope which is claimed. In the instant case, there Examiner has cited two instances of non-functional embodiments and the instant specification only provides one working example. Given the large breadth of the claims encompassing swapping any c-propeptide domain with any triple helix domain, absence evidence to the contrary, it is maintained that it would an be undue burden to test each possible combination for their ability to assemble into a procollagen molecule.

With respect to the enablement of transgenic animals, Examiner agrees that the methodology of transgenics is straightforward however, as set forth in the previous office actions the predictability of transgene behavior is not. Given the unpredictability recognized in the art of transgenics, it is maintained that the instant specification fails to provide the necessary guidance to overcome the art recognized limitations of producing the great breadth of any transgenic animal.